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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/147,770 04/28/99 DEL SOLDATO

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EXAMINER

TRAVERS, R

ART UNIT

PAPER NUMBER

1617

13

DATE MAILED:

08/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/147,770

Applicant(s)
Del Soldato et al

Examiner
RUSSELL TRAVERS

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1617



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 14, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, and 5-25 is/are pending in the application.
- 4a) Of the above, claim(s) 6-8 and 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 9, 10, and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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The response and amendment filed May 14, 2001 have been received and entered into the file.

Applicant's arguments filed May 14, 2001 have been fully considered but they are not deemed to be persuasive.

Claims 1-2, and 5-25 are presented for examination.

Applicant's election without traverse of Group I, claims 1-5 in Paper No. 10 is acknowledged.

Claims 6-8, and 11-20 reading on non-elected subject matter are withdrawn from consideration. Claims 1-2, 5, 9-10 and 21-25 will be examined to the extent they read on the elected subject matter.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

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Claims 1-2, 9-10 and 21-25 are rejected under 35 U.S.C. § 103 as being unpatentable over Merck Index #4852 and Morikawa et al.

Merck Index #4852 teach indomethacin as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as useful for treating inflammation. Morikawa et al teach indomethacin as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as useful for increasing the time to micturition, and increasing bladder pressure threshold. Compounds taught as useful for increasing the time to micturition, and increasing bladder pressure would have been seen as useful for treating urinary incontinence by the skilled artisan. Claims 1-2, 9-10 and 21-25, and the primary references, differ as to:

- 1) the recitation of those medicaments set forth in claims 9 and 10.

The skilled artisan, possessing a compound for a therapeutic use possesses that compounds analogs, homologs, isomers, bioisosteres, salts, acids and esters for the same use. To employ an analog, homolog, isomer, bioisostere, salts acid and ester for the same use therapeutic use would have been obvious to the skilled artisan. Prior art use for the same therapeutic purpose would have motivated the skilled artisan to employ indomethacin esters to the same therapeutic use and enjoy a reasonable expectation of therapeutic success.

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RESPONSE TO ARGUMENTS

As stated above, the instant claims read on analogs, homologs, isomers, bioisosteres, salts, acids and esters known for the same therapeutic use claimed herein. The skilled artisan possessing the core compounds for the same therapeutic purpose would have motivated the skilled artisan to employ indomethacin esters to the same therapeutic use enjoying a reasonable expectation of therapeutic success.

Applicants aver unexpected benefits residing in the claimed subject matter, yet fail to set forth evidence substantiating this belief. Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data provided by Applicants is neither convincing, nor reasonably commensurate in scope with the instant claims. Absent a convincing showing of unexpected benefits residing in the claimed subject matter; coupled with claims commensurate with the showing of unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103.

Attention is directed to page 51 (table 2) setting forth physiological effects of the parent compound and the claimed ester. Although no test for data reliability was offered, Examiner finds only a 10% difference between those effects provided by the

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parent compound, and the claimed ester. Examiner's 10% difference determination is, by necessity, based on the unlikely situation where no variation was seen between tests: a highly unlikely course of events. Absent a showing of **unexpected** benefits residing in the claimed subject matter, the instant claims remain properly rejected as obvious.

It is well known by the skilled artisan that carriers and excipients are employed to enhance the activity of active ingredients. Thus, the skilled artisan would expect conventional excipients and carriers to be useful concomitantly, absent information to the contrary. The instant carriers and excipients are not employed concomitantly in the prior art, thus only obviate their concomitant use.

Applicant's attention is drawn to In re Graf, 145 USPQ 197 (CCPA 1965) and In re Finsterwalder, 168 USPQ 530 (CCPA 1971) where the court ruled that when a substance is unpatentable under 35 USC 103, it is immaterial that applicant may have disclosed an obvious or unobvious further purpose or advantage for the substance.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

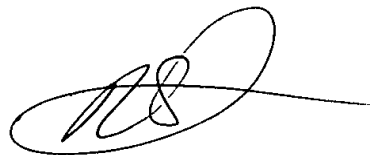
A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION.

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IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

A handwritten signature in black ink, appearing to read 'R. Travers', with a long horizontal line extending to the right.

**Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617**